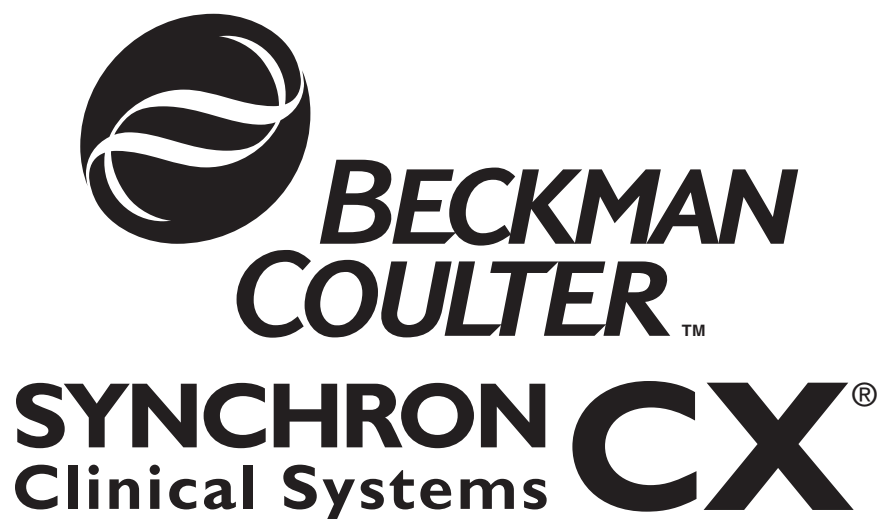


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A08578-AA
May 2003



Instructions For Use

For *In Vitro* Diagnostic Use

This manual is intended for
SYNCHRON CX[®]3 DELTA
SYNCHRON CX[®]4 PRO
SYNCHRON CX[®]5 PRO
SYNCHRON CX[®]7 PRO
SYNCHRON CX[®]9 PRO
SYNCHRON CX[®]4/CX[®]5/CX[®]7

EC REP

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CHAPTER 1 General Information

General Information

Intended Use

The SYNCHRON CX Systems are fully automated, computer-controlled clinical chemistry analyzers designed for the in-vitro determination of a variety of general chemistries, therapeutic drugs, and other chemistries. Analysis can be performed on serum, plasma, urine, or cerebrospinal fluid (CSF); (sample type is chemistry dependent).

Scope of This Manual

This manual covers general operating instructions, maintenance guidelines, and troubleshooting instructions for SYNCHRON CX Systems. Medical and diagnostic interpretation, or the clinical significance of chemistries or assays are not discussed. Refer to the reference materials below for detailed information.

Reference Manuals

Other manuals that accompany the system include:

- the SYNCHRON CX *Operating Instructions*, which contains detailed system description, comprehensive operating instructions, theory of operation, system calibration, programming procedures, quality control information, and maintenance procedures for SYNCHRON CX Systems.
- the SYNCHRON CX Clinical Systems *Chemistry Information Manual*, which contains specific chemistry information for the full range of analytes available on the SYNCHRON CX Systems.
- the SYNCHRON CX *Diagnostics and Troubleshooting Guide*, which provides diagnostic routines and troubleshooting guidelines in the event of system malfunction.
- the SYNCHRON CX PRO *Processing Guide*, which contains additional information and instructions for SYNCHRON CX Systems.
- the SYNCHRON CX *Performance Verification Manual*, which helps integrate the new SYNCHRON CX System into your daily laboratory routine.
- the SYNCHRON CX *Tip Sheets*, which provide additional information about the CX system.
- the SYNCHRON CX3 Delta *Maintenance, Diagnostics and Troubleshooting Manual*, for CX3 system details.
- the SYNCHRON CX3 Delta *Operating Instructions*, for CX3 operating details.

Shipping Damage

When you receive your new SYNCHRON CX System, visually inspect the shipping container for any possible damage. If there is damage, notify the Beckman Coulter Service Representative before his/her arrival at your facility to install your system.

If no damage is found to the shipping container, the Beckman Coulter Service Representative will supervise the unpacking of your system. If it is damaged in any way, the customer should file a claim with the carrier. If no damage is found, a visual and operational check of your system will be performed.

CHAPTER 2 System Description

System Description

Introduction

The following sections briefly describe the CX System, its specifications, and how it functions. In addition, important hazards to the analyzer, operator, and laboratory environment are identified.

CX System Configurations

The SYNCHRON CX System consists of various components and/or features. These components and features make up specific CX model configurations as described in the following table. The CX9PRO System is shown in Figure 2.1.

Table 2.1 CX System Configuration

CX Components and/or Features	CX Model Configuration
Ion-Selective Electrode (ISE) Module + Reaction Cup Chemistries	CX3 Analyzer
Basic random-access chemistry analyzer that includes the following components: <ul style="list-style-type: none">• CX Chemistry• Sample Handling Components• Operation and Control Components	CX4 Analyzer
CX4 + ISE Module	CX5 Analyzer
CX3 + CX4 (Refer to Figure 2.1)	CX7 or CX9 Analyzer
Basic CX4, CX5, CX7 and CX9 analyzer, plus the following features: <ul style="list-style-type: none">• Obstruction, Detection and Correction• Onboard Sample Dilution• Serum Indices• Reagent Metering via Modem	CX PRO Systems



Figure 2.1 CX9PRO System

CX System Specifications

Sunlight and Drafts

Do not place the system in direct sunlight or in drafts. Both of these conditions may affect the temperature control of the system.

Drain

The system should be located near a sink or floor drain to accommodate the waste effluent at a maximum rate of 1L/hr (CX3 Delta Systems), or 6.9 L/hr (CX4 Systems) or 7.1 L/hr (CX7 or CX 9 Systems). The drain must not be placed any higher than 39 in. (99.1 cm) above the floor.

Power Requirements

Table 2.2 Power Requirements

Item	Requirement
Operating range	220 to 240 VAC, RMS 15 A at low line, exclusive of power surge (CX4/CX7/CX9 Systems) 120/240 VAC Single Phase 90-132/180-264 VAC nominal voltage 4.25 A at 120 V/2.13 A at 240 V (CX3 Delta Systems)
Frequency	50/60 Hz
BTU generated	4972 BTU/Hour (CX4 Systems) 6400 BTU/Hour (CX7/CX9 Systems) 2040 BTU/Hour (CX3 Delta Systems)
Power connector	20 A current rating, Nema L6-20R twistlock Molded (CX3 Delta Systems)

Notes on System Power: The system can operate from any standard 3-wire electrical outlet and is wired as shipped from the factory to operate on 220V AC, 50/60 Hz. Line voltage from electrical outlets should be free of spikes, fluctuations, and dropouts for protection of electronic circuitry.



CAUTION

Only operate the system from a 3-wire power source. DO NOT use a 2-prong adapter or a 2-wire AC power source.

Environmental Conditions

Table 2.3 Environmental Conditions

Item	Requirement
Ambient temperature	+18°C to +30°C +18°C to +32°C (CX3 Delta Systems)
Warm-up time	2 hours after installation 1 hour after installation (CX3 Delta Systems)
Relative humidity	30% to 85%, non condensing at any temperature

Water Requirements

Table 2.4 Water Requirements

Item	Requirement
Flow Rate	6.5 L/hr continuous flow
Temperature	+15°C to +25°C.
Water quality	NCCLS Class II deionized water: <ul style="list-style-type: none">• Total bacteria count < 10 cfu/mL• Dissolved silicate < 0.1 mg/L• Specific resistivity: minimum of 1.0 megohmcm at 25°C• Filter to 0.2 microns absolute

ISE Module

The ISE module provides the measurement of sodium, potassium, calcium, chloride, and carbon dioxide (CO₂) in various body fluids. Sodium, potassium, calcium and chloride electrodes are ion-selective devices housed in a flow cell where a discrete sample analysis is made during each measurement cycle. The CO₂ measurement and reference electrodes, both of which are modified pH electrodes, are housed in the upper portion of the same flow cell.

The ISE module consists of 11 assemblies. Each assembly is described in detail within the SYNCHRON CX Clinical System *Operating Instructions*. Those assemblies include:

- Ratio Pump Assembly
- Pinch Valve Assembly
- Flow Mixers
- Debubbler Assemblies
- Peristaltic Pump Assembly
- Discrete Solenoid Valves
- Sample/Probe Crane Assembly
- Electrolyte Injection Cup
- Flow Cell Assembly
- Reagent Compartment
- Electronic/Circuit Board Compartment

CX3 Module

The CX3 module may be used as a stand-alone system, or in conjunction with a CX4 system. When the CX3 is connected to the CX4 analyzer, it relies on the CX4 for electrical power. The CX3 consists of the same ISE assemblies as listed above, plus a sample carousel. The CX3 is used for STAT determination of sodium, potassium, chloride, calcium, CO₂; all of which are measured with ion selective electrodes. In addition, the CX3 runs reaction cup chemistries for glucose, creatinine, total protein, and BUN (or urea).

CX4 Analyzer

The SYNCHRON CX4 system is a microprocessor-controlled, random-access chemistry analyzer that is designed to perform end point, rate, nonlinear quantitative assays, and qualitative drugs of abuse. The CX4 can house up to 24 chemistries in the reagent storage area. Reagents are contained in a three-compartment plastic cartridge. Each cartridge contains a bar code label that is automatically scanned during a reagent load procedure.

CX4 assemblies include the sample handling system, reagent handling system, syringes, cuvette reaction system, hydropneumatics, and electrical circuit boards.

Operation and Control Components

Operation of the CX analyzer is controlled by the computer, keyboard, video monitor, and push-button controls. Additionally, the video monitor and printer show test results, system functions, and alert information related to the status of the analyzer or programmed tests.

CXPRO Features

CXPRO Systems include four additional features. Those features are described below.

- **Obstruction Detection and Correction**

This feature detects the difference between a normal fluid sample and clotted sample by measuring the pressure encountered when the sample is aspirated. To accomplish this task, a pressure transducer is connected to each sample probe assembly. If a clot is detected, the system automatically attempts to remove the clot through two wash cycles. If the clot cannot be removed, an error message is posted. If the system detects a clot for three consecutive samples, the system completes those tasks not affected by the sample probe, and then shuts down. Refer to the SYNCHRON CX Clinical System *Operating Instructions* for further details.

- **Onboard Sample Dilution**

Certain urine and immunoprotein chemistries require the sample to be diluted before analysis. This feature automatically dilutes these samples onboard the system using a DIL1 cartridge. Refer to the SYNCHRON CX Clinical System *Chemistry Information Manual* for affected chemistries.

- **Serum Indices**

This feature allows the enabling or disabling of the Automatic Serum Index Function for all samples. When the serum indices feature is enabled for a sample, hemolysis, icterus, and libemia indices are automatically determined. A numeric value is printed below the Special Calculations area of the printed report. Serum indices are only intended for sample integrity assessment, not for patient diagnosis. Refer to the SYNCHRON CX Clinical System *Chemistry Information Manual* for additional information.

- **Reagent Metering Through Modem**

CX PRO Systems are equipped with an external modem to provide a communication interface for reagent metering and system troubleshooting.

Theory of Operation

Introduction

The SYNCHRON CX Systems are microprocessor-controlled, random-access clinical analyzers capable of processing a wide variety of operator-selected chemistries in a single run.

CX4 Chemistries

The optical system of the CX enables rate, endpoint, and nonlinear analyses to be performed simultaneously. These analyses are referred to as cartridge chemistries because the reagents are stored in cartridges.

CX3 Chemistries

The CX3 contains an Ion Selective Electrode assembly and four chemistry reaction modules. Refer to Table 2.5.

Table 2.5 Methodology and Modules Used with CX3 Chemistries

Chemistry	Methodology	Module
Sodium	Ion selective electrode (ISE)	ISE Flow cell
Potassium	Ion selective electrode	ISE Flow cell
Chloride	Ion selective electrode	ISE Flow cell
Carbon Dioxide	pH electrode	ISE Flow cell
Calcium	Ion selective electrode	ISE Flow cell
Blood Urea Nitrogen	Conductivity electrode	Blood Urea Nitrogen
Creatinine	Colorimetric	Creatinine
Glucose	Oxygen sensor	Glucose
Total Protein	Colorimetric	Total Protein

Operator Controls

The operator interfaces with various control devices such as the keyboard, video monitor and push-button controls during a routine run. Basic operating functions are controlled and reviewed from the video monitor. Calibration functions are also controlled from the video monitor. Information is selected and entered into the system through a keyboard.

Push-button controls are used to load samples, to start the test process, or to stop the process under certain conditions as described in Table 2.6 and Table 2.7.

Table 2.6 CX4/CX5/CX7/CX9 Control Buttons

Push-Button Control Type	Primary Function
Start	Starts the test process.
Stop	To stop the process. The stop button should be used only under the following conditions: <ul style="list-style-type: none">• During an emergency• To conduct a maintenance/repair activity• To home and realign mechanical components without rebooting
Load	Loads a sector into position on the sample carousel. The LOAD button is located near the Autoloader.
STAT Load	Provides a mechanism for placing STAT samples on the system without interrupting current sample processing.

Table 2.7 CX3 Control Buttons

Push-Button Control Type	Primary Function
Start	Starts the test process. The START button functions the same as the Start key on the keyboard.
Load	Loads a sector into position on the sample carousel. Provides a mechanism for placing STAT samples on the system without interrupting current sample processing.

Master Screen

CX System operating functions and programming functions are initiated from the Master Screen at the CX analyzer. Refer to Figure 2.2. The Master Screen is the trunk of the operator interface. It provides access to the most frequently used screens such as:

- Sample Program [F1]
- Reagent Load [F2]
- Calibration [F3]
- Special Function [F4]
- Quality Control [F5]
- Carousel Status [F6]
- System Parameters [F8]

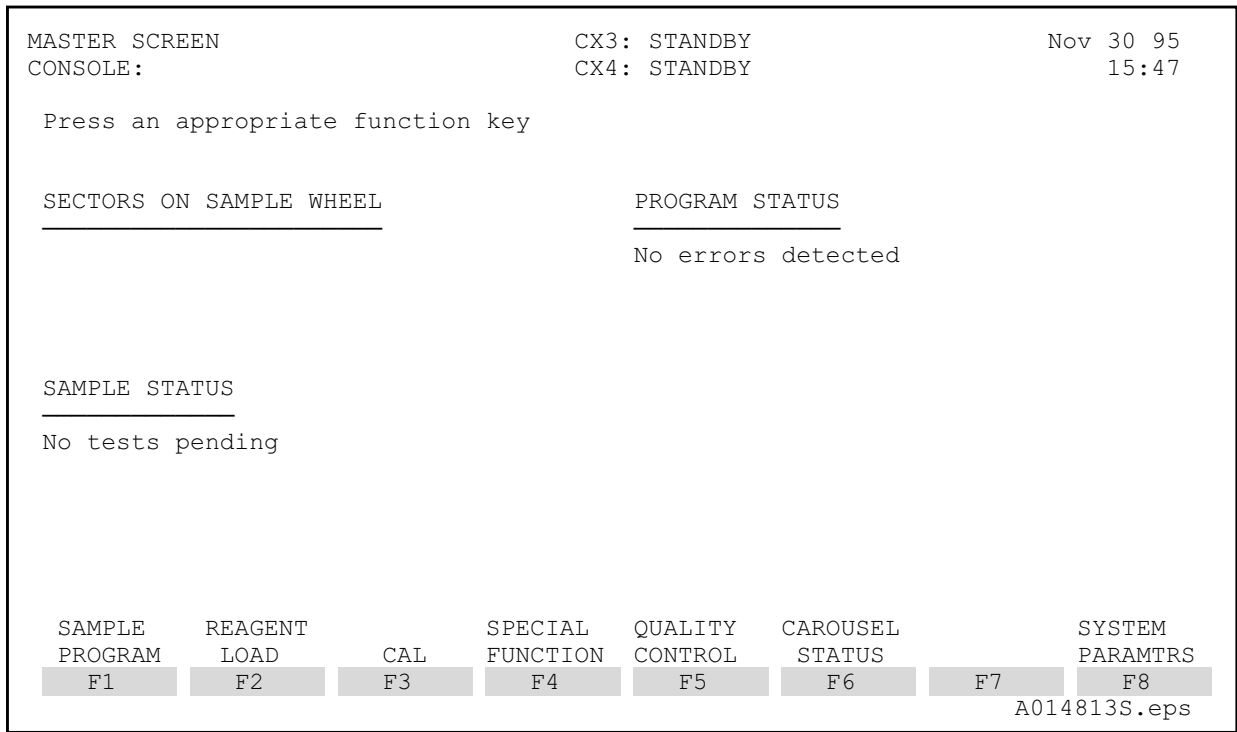


Figure 2.2 CX Master Screen

Precautions

Introduction

This section lists the precautions associated with the SYNCHRON CX System. Please read this information before operating the system.

Covers and Doors

To ensure optimum performance of the system, operate the system with reagent doors and all shields and covers in place.

Biohazard Precautions

All biohazard precautions should be observed when doing maintenance, service, or troubleshooting on the system. This includes, but may not be limited to, wearing gloves and eye shields and washing hands after working on contaminated portions of the system.

Reagent Precautions

The reagents and other chemical preparations used with the system will not normally cause adverse reactions; however, those persons with sensitive skin should wear protective rubber gloves before attempting to work with reagents and other chemical preparations.

Expired Reagents

The use of expired reagents may cause erroneous results.

Effect of Ten or Greater Urine Samples

After analysis of ten consecutive urine electrolytes, run one replicate of electrolytes on SYNCHRON CX Calibrator Level 2 in the serum mode. This will minimize the potential for chloride drift due to matrix effects of urine samples.

Diethylamine HCL and the Calcium ISE

Do not use controls containing diethylamine HCL. This adversely affects the calcium Ion-Selective Electrode (ISE).

Blood Barrier Collection Tubes

When blood collection tubes that contain physical barriers are used, extra care should be exercised to ensure that the barrier is tightly packed. Loose particles from the barrier could coat or plug the sample probe, flow cell, chemistry modules, electrolyte injection cup (EIC), or cuvette wash station.

Fibrin Clots

Samples should be free of all visible fibrin. Clots could coat or plug the sample probes, flow cell, chemistry modules, electrolyte injection cup (EIC), or cuvette wash station, leading to instrument malfunction and/or short sampling.

Insufficient ISE Reagent

Failure to operate the system with sufficient ISE reagent will result in erroneous chemistry results. In some cases, results will be obtained without reagents. Therefore, before starting any run, verify that sufficient reagent is available to complete the run.

ISE/CX3 Reagent Handling

Chemistry reagent containers should not be handled while the system is performing chemistry measurements.

Repetitive Refrigeration of Aqueous Calibrators

Repetitive refrigeration of SYNCHRON CX[®]/LX aqueous calibrators may facilitate crystal formation. Once removed from refrigerated storage, these calibrators should remain at room temperature. The calibrator once opened is stable for the period claimed in the accompanying package insert.

Alkaline Buffer Stability

The alkaline buffer reagent is stable for one month on the system. However, if a color change from pink to a lighter shade of pink should occur, replace the alkaline buffer with a fresh bottle of reagent.

Use of Beckman Coulter Microtubes™

- Beckman Coulter Microtubes™ are designed for use on specific SYNCHRON systems. Using the appropriate Microtube is essential for proper system operation.
- The sample height in the Microtube is critical for correct sample aspiration on all SYNCHRON systems.
- The use of Array[®] Microtubes™ (PN 448163 or PN 448162) on SYNCHRON Systems or the use of SYNCHRON Microtubes (PN 756776) on Array systems may result in short sampling, incorrect results, and/or sample probe damage.
- The use of non-Beckman Coulter, third party Microtubes, which have not been designed and tested on SYNCHRON Systems, may result in system damage and/or short sampling.

Cover and Shield Reinstallation

To prevent possible motion errors, verify the proper positioning of any removed and reinstalled cover or shield.

Sample Tubes Allowed

The use of sample tubes, other than the ones specified in this manual (or SYNCHRON CX Clinical System *Operating Instructions*), may cause system motion errors.

Replacement of Sectors

Sectors should be replaced every five years. Damaged sectors should not be used on the system or in the SPINCHRON™ Centrifuge.

Changes In Environmental Conditions

Changes in ambient temperatures and environmental conditions may result in a "reference drift" message. In this case, the electrolyte chemistries must be recalibrated.

Narrow Margin Bar Codes

The sample bar code reader on the CX can read *narrow-margin bar codes*. Because of the sensitivity needed to read narrow-margin bar codes, the labels must be high quality. They must be free from smudges, spots or other imperfections. An imperfection could be read as part of the Sample ID. This could cause an inaccurate read of the bar code.

Check Reagent Volumes

Check reagent volumes before starting a run. Failure to operate with sufficient reagent will result in erroneous chemistry results. In some cases, results will be obtained without proper amounts of reagents in the modules.

Clearing Samples NOT received by Host

DO NOT clear samples until results are received at the host and printed. Clearing samples manually or through host programming may cause the results to be received at the host and printed without the sample ID. Depending on the host implementation, this can cause lost sample results or sample results that merge with other sample results, producing duplicate tests or added tests.

Hazards

Introduction

This section lists the hazards associated with the SYNCHRON CX System. Please read this information before operating the system.

Electrical Ground

DO NOT UNDER ANY CIRCUMSTANCES OPERATE THE SYSTEM UNTIL AN ELECTRICAL GROUND IS PROVIDED AND THE POWER CORD IS PROPERLY CONNECTED TO THE GROUND.

Performing Service Procedures

Disconnect the power cord when performing service procedures such as replacing electronic or mechanical components.

Use of Three-Pronged Power Cord

The three-pronged power cord must only be connected to a matching three-wire grounded outlet. DO NOT use an adapter to connect the power plug to a two-pronged outlet.

Electric Shock

Replacement or servicing of any components where contact with bare, live hazardous parts could occur, possibly resulting in electric shock, should only be performed by qualified service personnel.

Flammable Materials

Do not use this system in the presence of flammable materials.

Moving Parts

Do not place hands near any moving parts while the system is in operation.

Biohazardous Materials

Observe all laboratory policies or procedures which pertain to handling of infectious and pathogenic materials.

System Operations and Specifications

System operation should be consistent with the power requirements as stated in the SPECIFICATIONS section of this chapter and in the SYNCHRON CX Clinical System *Operating Instructions*.

Tampering With Bar Code Reader

DO NOT tamper with or remove the housing of any bar code reader because of the laser-based nature of the readers and the potential hazard of looking directly at laser light. When the instrument is *running*, *homing*, or in *diagnostics*, the laser may be ON. At all other times the laser is OFF.

Sodium Azide Preservative

Reagents, calibrators and controls used with the system may contain small quantities (<0.1%) of sodium azide preservative. Refer to the related Material Safety Data Sheets (MSDS) for additional information.



CAUTION

Sodium azide preservative may form explosive compounds in metal drain lines. Refer to National Institute for Occupational Safety and Health Bulletin: Explosive Azide Hazards (8/18/76).

Avoid skin contact with reagent. Use water to wash reagent from skin.

CHAPTER 3 Load/Unload Reagent

Load/Unload Reagent

Introduction

This chapter describes how to load reagents onto the CX3 and CX4 systems. Always determine the reagent status before starting a run. Make sure reagent is loaded for all tests ordered and that all reagents have sufficient volume to complete the number of tests in the run. Then load reagents onto the system as necessary.

CX3/ISE Reagents Information

As shown in Figure 3.1, the CX3 and ISE reagents are located in the CX3/ISE reagent compartment. Reagents are stored in either 2-L, 1-L, or 500-mL bottles. The CX3 wash solution container is stored in a 10-L bottle.

Electrolyte reagents include the following:

- ISE Electrolyte Buffer
- CO₂ Acid Reagent
- ISE Electrolyte Reference
- CO₂ Alkaline Buffer

CX3 Cup Chemistry reagents include the following:

- Total Protein
- Glucose
- Creatinine
- Blood Urea Nitrogen



Figure 3.1 CX3/ISE Reagent Compartment

CX3/ISE reagent bottles are selected from the Reagent Load Screen and replaced as necessary according to volume. Reagent volume levels are automatically tracked by the system after the initial volume is set. When the operator replaces a new reagent bottle, the system assumes the bottle is 100% full. If the new bottle is not 100% full, the operator adjusts the reagent volume at the Reagent Load screen. CX3/ISE reagents can only be replaced when the CX3 is in Standby. Reagent expiration dates must be visually checked.

CX3/ISE Reagent Status and Load Procedure

Ensure adequate volumes of reagents are on the system to last the duration of the work shift. To check the reagent status, follow Steps 1-3 below. To load reagents, continue with Steps 4-8.

Step	Action
1	Place the CX3 into <i>Standby</i> operating mode.
2	From the Master Screen, press Reagent Load [F2].
3	Press CX3 Load/ISE Load [F3].
4	Move cursor to desired reagent(s) for loading. Press Select for all reagents to be loaded.
5	Press Continue [F4].
6	Place reagents onto the system. Refer to Figure 3.1
7	Press Prime [F1]. Selected reagent(s) will prime once the reagent load cycle is equivalent to 20 manual prime cycles.
8	Press Master Screen to return to Master Screen.

Determine Reagent Status for CX4

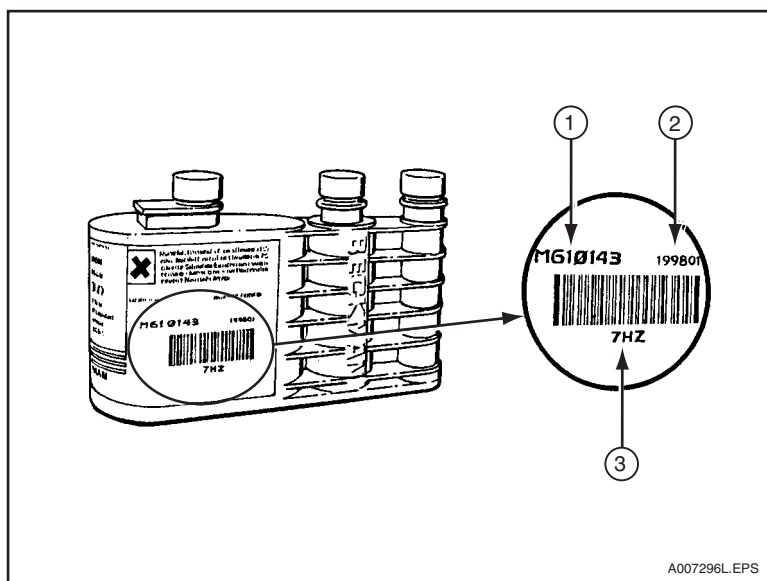
Ensure adequate volumes of reagents are on the system to last the duration of the work shift. Follow the procedure below.

Step	Action
1	From the Master Screen, press Reagent Load [F2].
2	Press Reagent Status [F5].
3	Verify that all reagents have a status of "OK" and that available tests are enough for the day's workload.
4	Press Print [F1] for a report.

CX4 Reagents Information

CX4 Systems use the cartridge bar code to identify and record data regarding reagent name, lot number (1), expiration date (2), serial number (3) of the cartridge. Refer to Figure 3.2. Additionally, the system retains calibration status of loaded and unloaded cartridges.

- CX4 reagents can be loaded while the system is running, waiting, or in *Standby*.
- Check reagent box or Reagent Preparation Card for reagent preparation instructions.
- Caps must be removed from the cartridge before loading.
- Check cartridges for bubbles in the reagent compartments before loading. Use an applicator stick to remove bubbles.



1. Lot Number
2. Expiration Date
3. Serial Number

Figure 3.2 CX4 Reagent Cartridge

CX4 Reagent Status and Load Procedure

Note: When loading CX4 reagents, the CX4 can be running, waiting, or in *Standby*.

Step	Action
1	From the Master Screen, press Reagent Load [F2] .
2	Move the cursor to the reagent carousel position to be loaded or unloaded.
3	Press Select for all reagent positions to be loaded or unloaded.
4	Press Auto Load [F1] .
5	When the screen states "Load cartridge at this time," lift the reagent access door (1) as shown in Figure 3.3. <div data-bbox="634 716 1258 1341" data-label="Image"></div>
6	Verify caps have been removed. Then verify that compartment necks are free from bubbles or excess fluid.

(1 of 2)

Step	Action, continued
7	<p>Place the reagent cartridge next to the bar code reader (1) as shown in Figure 3.4. Then slide the cartridge past the bar code reader until an audible signal is heard. This indicates that the bar code was read successfully. The reagent name should appear in the position selected on Load Screen.</p> <div data-bbox="634 470 1256 1094" data-label="Image"> </div> <p>Figure 3.4</p>
8	Insert the cartridge (2) into the reagent carousel as shown in Figure 3.4.
9	Close the reagent access door.
10	If more reagent cartridges need to be loaded, repeat Steps 5-8.
11	If done loading reagents, return to the Master Screen by pressing Master Screen .

(2 of 2)

CHAPTER 4 System Calibration

System Calibration

Introduction

System calibration is used to standardize the analysis of samples to existing conditions. Refer to the SYNCHRON CX Clinical Systems *Chemistry Information Manual* for detailed information regarding such conditions. In general, system calibration is required when:

- A new CX4 reagent cartridge is used (except when within lot calibration applies).
- A new ISE/CX3 chemistry reagent is loaded.
- At recommended calibration frequency intervals.
- Indicated by control results.
- Defined per your laboratory policy.
- Electronic or module adjustment.
- Calibration set point modification.
- New lot calibrator diskette load.
- Specific maintenance procedures as defined in the SYNCHRON CX *Operating Instructions*.
- Specific maintenance procedures as defined in the SYNCHRON CX3 Delta *Maintenance, Diagnostic and Troubleshooting Manual*.

Loading a Calibrator Diskette

Serum based calibrators require a calibrator diskette to be loaded on the system. The calibrator diskette is loaded only one time per lot number. Follow the steps below to check what lot number is currently loaded on the system.

Step	Action
1	From the Master Screen, press Cal [F3] .
2	Select Options [F6] .
3	Select <2> View Calibrator Acceptance Limits .
4	Use the Page Up or Page Down keys to find the lot number of the calibrator.

To load a new lot number of calibrator, follow the procedure below.

Step	Action								
1	Make sure the CX is in <i>Standby</i> .								
2	From the Master Screen, press Cal [F3] .								
3	Select Cal Options [F6] .								
4	Select <1> Load calibrator diskette .								
5	Insert the diskette into the disk drive and press [Enter] .								
6	<div>Verify that the lot number on the screen is the same as the lot number on the calibrator bottle.</div> <table border="1"> <tr> <th>If...</th><th>Then...</th></tr> <tr> <td>additional calibrator diskettes need to be loaded,</td><td>Press <Y> and repeat Step 5.</td></tr> <tr> <td>an incorrect calibrator diskette was inserted into disk drive,</td><td>Press <Y> and repeat Step 5.</td></tr> <tr> <td>no other calibrator diskettes need to be loaded,</td><td>Press <N>.</td></tr> </table>	If...	Then...	additional calibrator diskettes need to be loaded,	Press <Y> and repeat Step 5.	an incorrect calibrator diskette was inserted into disk drive,	Press <Y> and repeat Step 5.	no other calibrator diskettes need to be loaded,	Press <N> .
If...	Then...								
additional calibrator diskettes need to be loaded,	Press <Y> and repeat Step 5.								
an incorrect calibrator diskette was inserted into disk drive,	Press <Y> and repeat Step 5.								
no other calibrator diskettes need to be loaded,	Press <N> .								
7	Remove the diskette from the disk drive.								
8	Press the [Master Screen] key to exit and return to the Master Screen.								

Determine Calibration Status for Calibrator Containers With Bar Code Labels

Ensure chemistries have a calibration status of "Calibrated," and will not time out during a work shift. The Time Out column displays the time remaining for a calibration in days, hours, and minutes. If the calibrator container has a bar code label, determine the calibration status for CX chemistries as follows:

Step	Action
1	From the Master Screen, press Cal [F3] .
2	Using the cursor, check how much calibration time is left for each chemistry.

Assigning Bar Code IDs to Calibrators

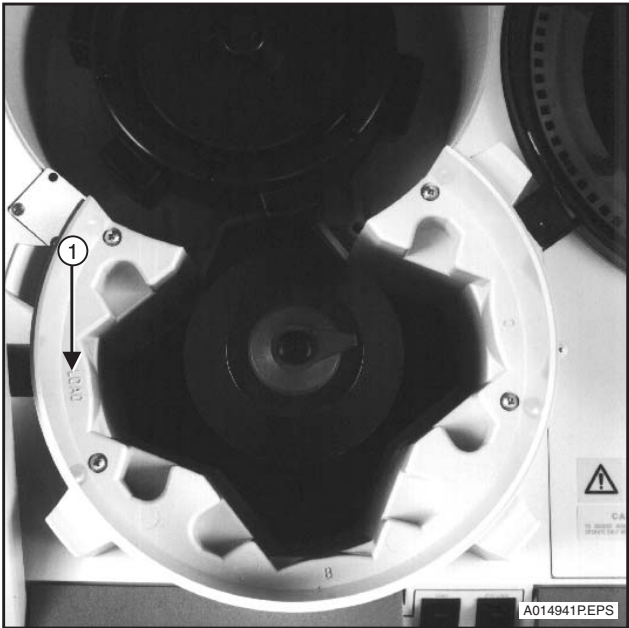
When the system is in the bar code mode, bar codes are assigned to calibrators. Chemistries are then requested for calibration. Assign bar code IDs to calibrators as follows:

Step	Action
1	From the Master Screen, press Cal [F3] .
2	From the Calibration Screen, verify if the reagent pack to be calibrated has an assigned bar code ID.
3	To assign a bar code, press Cal Options [F6] .
4	From the Cal Options Screen, cursor and select option 7, Assign bar code .
5	Locate the appropriate calibrator(s) for the reagents to be calibrated. Enter the bar code ID. Press the [Enter] key after each bar code entry. Use the [Page Up/Page Down] keys to access additional calibrator information.
6	Press the [Prev Screen] key to return to the Calibration Screen.

CX Calibration Procedure with Bar Coded Containers

Step	Action
1	From the Master Screen, press Cal [F3] .
2	Using the cursor and the [Select] key, highlight those chemistries that require calibration.
3	Load bar code labeled containers containing the correct calibrator in a sector. The bar code label must be facing forward in the sector.

(1 of 3)

Step	Action, continued
4	<p data-bbox="423 285 1461 352">Refer to Figure 4.1. Remove the Autoloader cover. Place the sector into the Load position (1) at the CX autoloader</p> <div data-bbox="630 394 1255 1018">  </div> <p data-bbox="581 1041 711 1075">Figure 4.1</p>

(2 of 3)

Step	Action, continued							
5	<table><tr><th>If...</th><th>Then...</th></tr><tr><td>the system is running,</td><td>Press the <LOAD> button (1) located near the Autoloader. Refer to Figure 4.2.</td></tr><tr><td>the system is in <i>Standby</i>,</td><td>Return to the Master Screen by pressing the [Master Screen] key. Then press the [Start] key located at the keyboard.</td></tr></table>		If...	Then...	the system is running,	Press the <LOAD> button (1) located near the Autoloader. Refer to Figure 4.2.	the system is in <i>Standby</i> ,	Return to the Master Screen by pressing the [Master Screen] key. Then press the [Start] key located at the keyboard.
If...	Then...							
the system is running,	Press the <LOAD> button (1) located near the Autoloader. Refer to Figure 4.2.							
the system is in <i>Standby</i> ,	Return to the Master Screen by pressing the [Master Screen] key. Then press the [Start] key located at the keyboard.							

Figure 4.2

(3 of 3)

Determine Calibration Status for Calibrator Containers Without Bar Code Labels

Ensure the chemistries have a calibration status of "Calibrated," and will not time out during a work shift. The Time Out column displays the time remaining for a calibration in days, hours, and minutes. If the calibrator container has a bar code label, determine the calibrating status for CX chemistries as follows:

Step	Action
1	From the Master Screen, press Cal [F3] .
2	Using the cursor, check how much calibration time is left for each chemistry.

Calibration Procedure without Bar Coded Containers

Step	Action
1	From the Master Screen, press Cal [F3] .
2	Using the cursor and the [Select] key, highlight those chemistries that require calibration.
3	Press Man Cup Assgnmnt [F1] (CX5 Systems), or Assign Sec/Cup [F1] (CX7/9 Systems).
4	Enter the sector number for each assigned calibrator. Then press the [Enter] key.
5	Enter the Calibrator Identification number for each calibrator. Then press the [Enter] key.
6	To view the calibration assignments, press Manual Cup List [F2] . To print the assignments, press Print [F1] .
7	Load calibrators into the assigned sector and cup positions.
8	Place the sector in the Load position of the Autoloader. Refer to Figure 4.1.
9	If the system is running, press the <LOAD> button located near the Autoloader. Refer to Figure 4.2. If the system is in <i>Standby</i> , return to the Master Screen by pressing the [Master Screen] key. Then press the [Start] key located at the keyboard.

Determine Calibration Status in Sector/Cup Mode

Ensure the chemistries have a calibration status of "Calibrated," and will not time out during a work shift. The Time Out column displays the time remaining for a calibration in days, hours, and minutes. Determine the calibration status for CX chemistries as follows:

Step	Action
1	From the Master Screen, press Cal [F3] .
2	Using the cursor, check how much calibration time is left for each chemistry.

Calibration Procedure for Sector/Cup Mode

The Sector/Cup mode is used when a bar code label is unavailable or unsuitable, or if the sample must be run in a cup. The Sector/Cup operating mode allows the operator to assign a bar code ID directly to a sector/cup position.

Step	Action
1	From the Master Screen, press Cal [F3] .
2	Using the cursor and the [Select] key, highlight those chemistries that require calibration.
3	Press Cal Cup Assgnmnt [F1] .
4	Enter the sector number for each assigned calibrator. Then press the [Enter] key.
5	To view the calibration assignments, press Cal Load List [F2] . To print the assignments, press Print [F1] .
6	Load calibrators in the sector and cup positions as they appear on the calibration load list.
7	Place the sector in the Load position of the Autoloader. Refer to Figure 4.1.
8	<p>If the system is running, press the <LOAD> button located near the Autoloader. Refer to Figure 4.2.</p> <p>If the system is in <i>Standby</i>, return to the Master Screen by pressing the [Master Screen] key. Then press the [Start] key located at the keyboard.</p>

CHAPTER 5 Quality Control

Quality Control

Introduction

This task is performed when your laboratory protocol indicates that control material should be analyzed. A daily analysis of at least two levels of control materials is highly recommended. In addition, these controls should be run with each new calibration, with each new lot of reagents, and after specific maintenance or troubleshooting activities. However, users should determine their own frequency based on the NCCLS Proposed Guideline C24-P INTERNAL QUALITY CONTROL TESTING: PRINCIPLES AND DEFINITIONS.

When defining controls, Control IDs should be as descriptive as possible. Refer to the SYNCHRON CX *Operating Instructions* for further details. The following procedures describe how to run control samples.

Programming Quality Control (QC) Test(s) in Bar Code Mode

NOTICE

To process all QC tests for that QC file, place the QC material in the correct bar code labeled sample container. Then process the samples as instructed in CHAPTER 6, *Process Programmed Samples*, Bar Code Mode. No programming is necessary.

Program Quality Control samples in the Bar Code Mode as follows:

Step	Action
1	From the Master Screen, press Sample Program [F1].
2	Press Program Samples [F1].
3	Press Select Control [F3].
4	Enter the Item Number of the Quality Control and press the [Enter] key.
5	Press Select Bar Code [F2].
6	Enter the Bar Code ID number and press the [Enter] key.
7	Using the arrow keys, move the cursor to desired tests and press the [Select] key.
8	Press New Sample [F8]. Continue to process QC samples as instructed in CHAPTER 6, <i>Process Programmed Samples</i> , Bar Code Mode. To program additional QC samples, repeat Steps 3-7.

Programming Quality Control Samples in Sector/Cup Mode

Step	Action
1	From the Master Screen, press Sample Program [F1] .
2	Press Program Sectors [F1] .
3	Enter the sector number and press the [Enter] key.
4	Press Select Control [F3] .
5	Enter the Item Number of the Quality Control and press [Enter] key.
6	Enter the Sample ID number.
7	Using the arrow keys, move the cursor to desired tests and press the [Select] key.
8	Press Next Cup [F8] . Then press Prev Screen and Load List [F3] to view sector/cup position of each sample. Press Print [F1] for printed copy. To program additional QC samples, repeat Steps 4-8.
9	Load the sample(s) into their assigned sector/cup position(s).
10	Place the sector in the Load position of the Autoloader.
11	If the system is running, press the <LOAD> button near the CX Autoloader. If the system is in <i>Standby</i> , return to the Master Screen by pressing the [Master Screen] key. Then press the [Start] key on the keyboard.

CHAPTER 6 Sample Programming and Processing

Sample Programming and Processing

Introduction

Sample programming provides the ability to identify samples, select tests to run, describe samples, and designate how to run samples. Samples are programmed through a host computer or Laboratory Information System (LIS) or at the analyzer. The minimum information required to save a sample program includes:

- a sample ID or a sector and cup position assignment
- and one test selection

Test selections are assigned by the use of panels or by the selection of individual tests. Samples may be described and defined through sample type, sample comment, patient ID, and patient demographic functions. A sample can be programmed as a control sample or as a STAT for priority processing. Once programmed, samples are placed on the CX autoloader for processing.

NOTICE

Refer to the Sample Tube Template and the Reagent Preparation Card for minimum sample volumes and sample preparation activities. Sample volumes and reagent preparation information can also be found in the SYNCHRON CX Clinical System *Chemistry Information Manual*



CAUTION

If your LIS or normal workflow requires the reuse of sample IDs, the sample programming should be cleared from the CX at a time interval that is less than the shortest time of sample ID reuse. If this warning is not followed, results from the new request will be merged with tests from incomplete samples that previously used that ID.

Program Samples and Controls

Refer to this chapter for Sample information and CHAPTER 4, *System Calibration* for Control programming information.

Prepare Samples




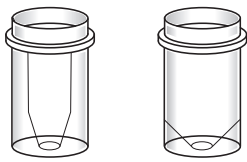


Minimum Sample Volume

A minimum sample volume is required to run tests. To determine what volume of sample to use, refer to the Sample Tube Template or the SYNCHRON CX Clinical Systems *Chemistry Information Manual*.

Sample Preparation by Container Type

Table 6.1 shows how to prepare different sample containers.

Table 6.1 Preparation of Sample Containers

If running a sample from a...	Then...
Primary Tube  <small>A014510L.EPS</small>	<ul style="list-style-type: none"> • Use the sampling template to determine adequate sample volume. • Remove the stopper.
Secondary Tube  <small>A014496L.EPS</small>	<ul style="list-style-type: none"> • Remove the cap. • Determine sufficient volume. • Check for fibrin or other materials resulting from storage.
SYNCHRON Microtube™  <small>A014497L.EPS</small>	<ul style="list-style-type: none"> • Pipette the sample into a SYNCHRON Microtube™. • Verify there are no bubbles at the bottom of the tube. • Place into a 13 × 100 mm sector.
If running a sample from an...	Then...
Autoanalyzer Cup  <small>A014498L.EPS</small>	<ul style="list-style-type: none"> • Place the cup into a sector. <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> • Verify there are no bubbles in sample.
BD Microtainer  <small>A014499L.EPS</small>	<ul style="list-style-type: none"> • Place microtainer in adapter P/N 472987. • (refer to figure to the right) • Verify there are no bubbles in sample.  <small>A014500L.EPS</small>

Bar Code Labeling

The use of bar code labels is a highly accurate and efficient method for identifying and processing laboratory samples. However, the system must be able to identify and read every bar code label to process each sample correctly. The following paragraphs provide some basic information pertaining to bar code labels. Additional bar code information can be found in the SYNCHRON CX Clinical Systems *Operating Instructions*.

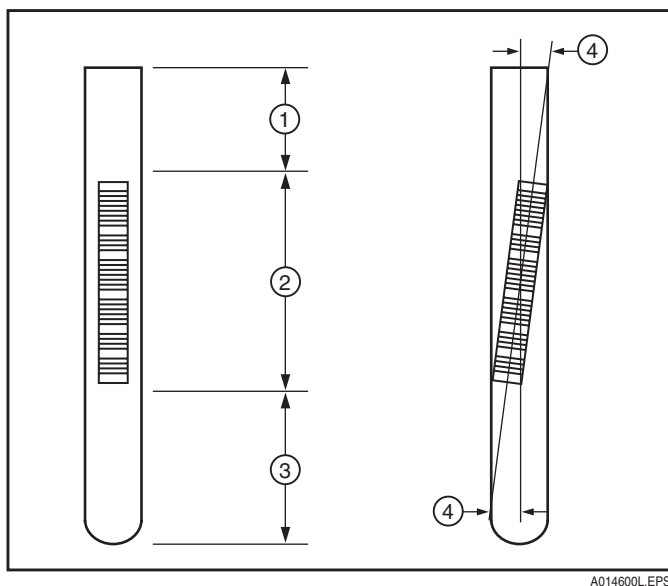


CAUTION

A misread label can cause one sample ID to be read as another. The laboratory's process for printing, placing, and meeting all bar code specifications is important to achieve highly accurate reading. Follow the bar code label specifications to keep the rate of misread labels to a minimum.

Bar Code Label Placement

Bar code labels must be applied to each sample tube in the correct location so that the bar code reader can read the bar code. The following diagram (Figure 6.1) describes how to place the label on a sample tube.



A014600L.EPS

1. 14 mm (0.55 inch) Minimum
2. Label Placement Area
3. 20mm (0.78 inch) Minimum
4. 7.5 Degree Maximum

Figure 6.1 Bar Code Label Placement

Programming Sample Test(s) in Bar Code Mode

Step	Action
1	From the Master Screen, press Sample Program [F1] .
2	Press Program Samples [F1] .
3	<p>Enter the Sample ID and press the [Enter] key.</p> <p>(Note: Up to 11 alphanumeric characters can be used when entering Sample IDs. Invalid Sample ID characters include *, ?, \$, space, comma, and semi-colon. Alpha characters must be entered in upper case.)</p> <p>Using the arrow keys, move the cursor to other demographic fields. Press Options [F1] to modify sample information.</p>
4	<p>Press [Select] to highlight tests for processing.</p> <p style="text-align: center;">NOTICE</p> <p>Press STAT [F4] to program the sample as a STAT and activate the STAT mode. STAT is only active for the current cup or sample ID being programmed.</p>
5	To process these samples, continue to <i>Process Programmed Samples - Bar Code Mode</i> within this chapter.
6	To program additional samples, press New Sample [F8] and repeat Steps 3-5.

Process Programmed Samples in Bar Code Mode With Bar Coded Sample Containers

Step	Action
1	From the Master Screen, load bar code labeled sample containers into any sector. The bar code label must be facing forward in the sector.
2	Place the sector in the Load position of the CX Autoloader.
3	<p>If the system is running, press the <LOAD> button near the Autoloader. Use the [STAT Load] button to immediately load a stat onto the system.</p> <p>If the system is in <i>Standby</i>, return to the Master Screen by pressing the [Master Screen] key. Then press the [Start] key on the keyboard to begin processing.</p>

Process Programmed Samples in Bar Code Mode Without Bar Coded Sample Containers

Step	Action
1	From the Master Screen, press Sample Program [F1] .
2	Press Assign Sec/Cup [F6] . This lets the system know where to locate each sample container without a bar code label.
3	Enter the sector number for the assigned samples and press the [Enter] key.
4	Enter the sample/bar code ID in the cup position(s) and press the [Enter] key. (Note: Up to 11 alphanumeric characters can be used when entering Sample IDs. Invalid Sample ID characters include *, ?, \$, space, comma, and semi-colon. Alpha characters must be entered in upper case.)
5	To view sample assignments, press Manual Cup List [F2] . To obtain a printed list, press Print [F1] . To assign samples to additional sectors, press Next Sector [F8] and repeat Steps 3-5. <div style="text-align: center;">NOTICE</div> Press STAT [F4] to program the sample as a STAT and activate the STAT mode. STAT is only active for the current cup or sample ID being programmed.
6	Load the samples into their assigned sector/cup positions.
7	Place the sector in the Load position on the CX Autoloader.
8	If the system is running, press the <LOAD> button near the Autoloader. Use the [STAT Load] button to immediately load a stat onto the system. If the system is in <i>Standby</i> , return to the Master Screen by pressing the [Master Screen] key. Then press the [Start] key on the keyboard to begin processing.

Rerunning a Sample (Bar Code Mode)

This option allows the operator to rerun a completed sample in the Bar Code Mode. The results obtained overwrite existing results. The original results will no longer be available.

Step	Action								
1	From the Master Screen, press Sample Program [F1] .								
2	Press Rerun Samples [F4] .								
3	Enter the sector numbers for the rerun.								
4	<p>Using the cursor, select the desired Rerun Option (Sample IDs, Time/Date, Queue Number) and press the [Enter] key.</p> <table border="1"> <thead> <tr> <th>If...</th><th>Then...</th></tr> </thead> <tbody> <tr> <td><i>Sample ID(s)</i> was selected,</td><td>enter the sample ID(s) to be programmed for the rerun. Press [Enter] after each ID. When sample ID entry is completed, press End Sample ID [F8].</td></tr> <tr> <td><i>Time/Date</i> was selected,</td><td>enter the time and date retrieval range for the sample rerun and press the Prev Screen key.</td></tr> <tr> <td><i>Queue Number</i> was selected,</td><td>enter the queue number(s) or range to be rerun.</td></tr> </tbody> </table>	If...	Then...	<i>Sample ID(s)</i> was selected,	enter the sample ID(s) to be programmed for the rerun. Press [Enter] after each ID. When sample ID entry is completed, press End Sample ID [F8] .	<i>Time/Date</i> was selected,	enter the time and date retrieval range for the sample rerun and press the Prev Screen key.	<i>Queue Number</i> was selected,	enter the queue number(s) or range to be rerun.
If...	Then...								
<i>Sample ID(s)</i> was selected,	enter the sample ID(s) to be programmed for the rerun. Press [Enter] after each ID. When sample ID entry is completed, press End Sample ID [F8] .								
<i>Time/Date</i> was selected,	enter the time and date retrieval range for the sample rerun and press the Prev Screen key.								
<i>Queue Number</i> was selected,	enter the queue number(s) or range to be rerun.								
5	<p>Using the cursor, select the next Rerun Option (Rerun all tests, Rerun specific tests, Batch rerun).</p> <p>The option to add or delete tests, to enter an off-line dilution factor, or to assign the test status to STAT is available at this time.</p>								
6	Load sample(s) into their assigned sector/cup position(s).								
7	Place the sector in the Load position of the CX Autoloader.								
8	<p>If the system is running, press the <LOAD> button near the Autoloader. Use the [STAT Load] button to immediately load a stat onto the system.</p> <p>If the system is in <i>Standby</i>, return to the Master Screen by pressing the [Master Screen] key. Then press the [Start] key on the keyboard to begin processing.</p>								

Program Sample Test(s) in Sector Cup Mode

Step	Action
1	From the Master Screen, press Sample Program [F1] .
2	Press Program Sectors [F1] .
3	Enter an available sector number and press the [Enter] key.
4	<p>Enter the sample ID and press the [Enter] key.</p> <p>(Note: Up to 11 alphanumeric characters can be used when entering Sample IDs. Invalid Sample ID characters include *, ?, \$, space, comma, and semi-colon. Alpha characters must be entered in upper case.)</p> <p>Using the arrow keys, move the cursor to other demographic fields. Then press the [Enter] key. Press Options [F1] to modify sample information.</p>
5	<p>Press [Select] to highlight tests for processing.</p> <p style="text-align: center;">NOTICE</p> <p>Press STAT [F4] to program the sample as a STAT and activate the STAT mode. STAT is only active for the current cup or sample ID being programmed.</p>
6	<p>To view sector/cup positions of each sample, press Prev Screen and Load List [F3]. To obtain a printed list, press Print [F1].</p> <p>To program additional samples, press Next Cup [F8] and repeat Steps 4-6.</p>
7	Load the sample(s) into their assigned sector/cup position(s).
8	Place the sector in the Load position on the CX Autoloader.
9	<p>If the system is running, press the <LOAD> button near the Autoloader. Use the [STAT Load] button to immediately load a stat onto the system.</p> <p>If the system is in <i>Standby</i>, return to the Master Screen by pressing the [Master Screen] key. Then press the [Start] key on the keyboard to begin processing.</p>

Rerunning a Sample (Sector/Cup Mode)

This option allows the operator to rerun a completed sample in the Sector Cup Mode. The results obtained overwrites existing results. The original results will no longer be available.

Step	Action								
1	From the Master Screen, press Sample Program [F1] .								
2	Press Rerun Samples [F4] .								
3	Enter the sector numbers for the rerun.								
4	<p>Move the cursor to select the desired Rerun Option and press the [Enter] key.</p> <p>Press Option 1 to rerun all cups in sector(s). OR Press Option 2 to rerun specific cups in the sectors.</p> <table border="1"> <thead> <tr> <th>If...</th><th>Then...</th></tr> </thead> <tbody> <tr> <td>Option 1 was selected,</td><td>all cups originally programmed for the sectors are selected for rerun. Select the rerun option for the sector and cup position(s).</td></tr> <tr> <td>Option 2 was selected,</td><td>enter the cups to be rerun and press the [Enter] key.</td></tr> <tr> <td>multiple sectors are requested for rerun,</td><td>enter the cup for each sector and press the [Enter] key.</td></tr> </tbody> </table>	If...	Then...	Option 1 was selected,	all cups originally programmed for the sectors are selected for rerun. Select the rerun option for the sector and cup position(s).	Option 2 was selected,	enter the cups to be rerun and press the [Enter] key.	multiple sectors are requested for rerun,	enter the cup for each sector and press the [Enter] key.
If...	Then...								
Option 1 was selected,	all cups originally programmed for the sectors are selected for rerun. Select the rerun option for the sector and cup position(s).								
Option 2 was selected,	enter the cups to be rerun and press the [Enter] key.								
multiple sectors are requested for rerun,	enter the cup for each sector and press the [Enter] key.								
5	<p>Using the cursor, select the next Rerun Option (Rerun all tests, Rerun specific tests, Batch rerun).</p> <p>The option to add or delete tests, to enter an off-line dilution factor, or to assign the test status to STAT is available at this time.</p>								
6	Load the sample(s) into their assigned sector/cup position(s).								
7	Place the sector in the Load position on the CX Autoloader.								
8	<p>If the system is running, press the <LOAD> button near the Autoloader. Use the [STAT Load] button to immediately load a stat onto the system.</p> <p>If the system is in <i>Standby</i>, return to the Master Screen by pressing the [Master Screen] key. Then press the [Start] key on the keyboard to begin processing.</p>								

When to Clear Samples

If...	Then...
Sample programming has been completed,	clear sample programming
A sample ID has to be reused,	clear that sample ID first.
A sector/cup can not be programmed due to previous programming,	clear that programming.

Clearing a Sector (Sector/Cup Mode)

Step	Action
1	From the Master Screen, press Sample Program [F1].
2	Press Clear Samples [F5].
3	Enter the number of sectors to be cleared and press the [Enter] key. Use the (,) or (-) key to enter multiple sectors.
4	Press Master Screen to exit and return to the Master Screen.

Clearing a Sample ID from a Sample Program (Sector/Cup Mode)

Step	Action
1	From the Master Screen, press Sample Program [F1].
2	Press Program Sectors [F1].
3	Enter the sector numbers to be cleared and press the [Enter] key. Move the cursor to the cup field and enter the cup position to be cleared.
4	Press the [Clear] key on the keyboard. The Sample ID will be cleared from the field and the sample program will remain.

Clearing a Sample ID and Associated Programming (Bar Code Mode)

Step	Action
1	From the Master Screen, press Sample Program [F1].
2	Press Clear Samples [F5].
3	Select a clear option (Sample ID, Time/Date, or Queue Number).
4	From the selected clear option screen, enter the sample ID, the time/date range, or the queue number to be cleared, and press the [Enter] key.

Clearing a Sample Program (Bar Code Mode)

Step	Action
1	From the Master Screen, press Sample Program [F1] .
2	Press Program Samples [F1] .
3	Enter the Sample ID number to be cleared.
4	Press Clear Sample [F6] .
5	To clear the program on the screen, enter the letter Y and press the [Enter] key at the prompt.

Clearing a Sample ID from a Sample Program

Step	Action
1	From the Master Screen, press Sample Program [F1] .
2	Press Program Samples [F1] .
3	Enter the Sample ID to be cleared. Press [Enter] and cursor back to the Sample ID field.
4	Press the [Clear] key. The sample ID will be cleared from the field and the sample program will remain.

Pre-Run Summary Report

This report lists CX4 reagent names and locations, number of tests per cartridge, the reagent status, and the calibration status. For CX3 chemistries, the report lists the total tests programmed, the reagent status, and the calibration status. Follow the steps below to print a Pre-Run Summary Report.

Step	Action
1	From the Master Screen, press Sample Program [F1] .
2	Press Pre Run Summary [F7] . The report will be automatically printed.
3	Press Master Screen to return to the Master Screen.

Post-Run Summary Report

This report lists the samples that are pending or incomplete, and an explanation of the status. Incomplete or pending tests are generated due to a reagent or calibration status. Follow the steps below to print a Post-Run Summary Report.

Step	Action
1	From the Master Screen, press Sample Program [F1] .
2	Press Post Run Summary [F8] . The report will be automatically printed.
3	Press Master Screen to return to the Master Screen.

CHAPTER 7 Other Activities

Other Activities

Introduction

This chapter describes several activities including homing the CX, rebooting the CX computer, and system power down/power up procedures.

Homing the CX

Step	Action
1	Press the [Master Screen] key.
2	Press the [Sys Home] key. The CX system will home and prime automatically.

Reboot the Computer (CX Console)

Step	Action
1	The CX must be in <i>Standby</i> or <i>Stopped</i> .
2	From the Master Screen, press the [Sys Idle] key.
3	Press the [Y] key, followed by the [Enter] key.
4	Press the Resume [F4] key.
5	Press the [Y] key, followed by the [Enter] key. Wait until the "Press Prev Screen to Continue" messages appears.
6	Press the [Prev Screen] key.
7	Press Reboot the CX Console [F2] . The CX system will reboot automatically. The system is ready for normal operation when the Master Screen appears.

Power Down the CX

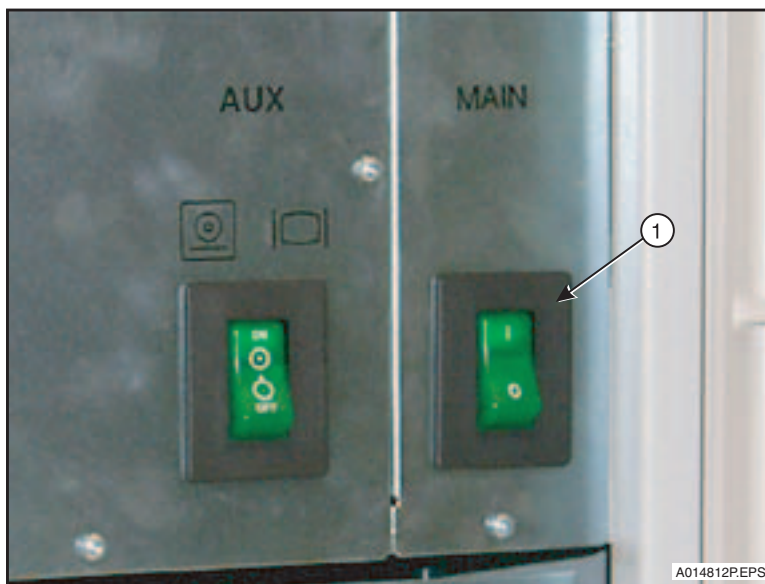
The Power Down procedure is used for temporary shutdown. Only perform the power down procedure when instructed by Beckman Coulter Technical Support or when instructed by a manual procedure (such as replacing parts). The CX System should remain ON when not in use to allow automatic priming.

Power Down Procedure

Step	Action
1	The CX must be in <i>Standby</i> or <i>Stopped</i> .
2	From the Master Screen, press the [Sys Idle] key.
3	Press the [Y] key, followed by the [Enter] key.
4	Press Resume [F4] .
5	Press the [Y] key, followed by the [Enter] key. Wait until the "Press Prev Screen to Continue" message appears.
6	Press the [Prev Screen] key.
7	Press Shut down the CX Console [F1] .
8	Turn the CX computer [OFF] .
9	Turn the CX analyzer [OFF] at the main switch. Refer to Figure 7.1.
10	Reset the UPS (Uninterrupted Power Supply) by turning the power switch [OFF] , and then turning it back [ON] .
11	The CX system is now powered down.

Power Up the CX

Step	Action
1	To power up the CX, turn [ON] the main switch located behind the lower right door. Refer to Figure 7.1.
2	Turn [ON] the CX computer. The CX System will automatically reboot in approximately 10 minutes.
3	When the Master Screen appears, resume normal operations.



1. ON/OFF switch

Figure 7.1 CX ON/OFF switch

CHAPTER 8 Maintenance

CX Maintenance Procedures

Introduction

The SYNCHRON CX System requires scheduled maintenance and periodic maintenance to operate correctly. Scheduled maintenance activities are performed at the following intervals:

- Daily
- Weekly
- Two-week
- Monthly
- Two-month
- Three-month
- Six-month

Refer to the SYNCHRON CX *Operating Instructions*, the SYNCHRON CX *Instrument Logbook*, and the SYNCHRON CX *Diagnostics and Troubleshooting Manual Guide* for performing all maintenance procedures.

CX System Periodic Maintenance

The following steps are necessary to initiate some periodic maintenance procedures for the CX System.

Step	Action
1	From the Master Screen, press Special Function [F4] .
2	Using the cursor, select <6> Maintenance Procedures and press [Enter]. Nine maintenance procedures appear on the Maintenance Procedures screen.
3	Using the cursor, select the desired maintenance procedure and press [Enter].
4	Follow the instructions on the screen for each maintenance procedure.

CX3 Daily Maintenance

Clean

Outside of sample probe; clean probe interior with cleaning stylus

Check

- Reagent levels and expirations dates
- Status monitor
- Fluid level of damper assembly (adjust if needed to 1/2 to 3/4 full)

Prime

CX3 reagents and observe for leaks, crimps, and proper movement of assemblies including reaction cup stirrers

CX3 Weekly Maintenance

Inspect/Clean

- In-line filters at peri-pump assemblies (clean or replace if needed)
- Flow cell 50% bleach (if >350 samples per day are run)

Adjust

Pinch Valve Tubing

- E cam pinch valve tubing
- C cam pinch valve tubing and check line #124
- Solenoids valve tubing

Bleach

Calcium reaction cup and stirrer (CA cup users only)

CX3 Two-Week Maintenance

Clean

- Flow cell 50% bleach
- Glucose electrode reaction cup and stirrer; recharge electrode
- Creatinine reaction cup and stirrer
- TP reaction cup and stirrer (on TP configured systems only)

CX3 Monthly Maintenance

Clean

- BUN electrode, reaction cup and stirrer
- Sample Bar Code Reader Window (CX3 Delta Systems)

Replace

- Alkaline Buffer peri-pump tubing and Alkaline Buffer reagent

CX3 Two-Month Maintenance

Clean

- Chloride electrode
- CX3 Electronics compartment and power supply compartment air filter. Replace filter if needed.

Replace

- CX3 peri-pump tubing
- In-line filters at peri-pump assemblies

CX3 Six-Month Maintenance

Clean

Electrolyte drain

Replace

- Potassium electrode tip
- Calcium electrode tip (Ca ISE users only)
- Ratio pump quad-rings

CX4 Daily Maintenance

Clean

Outside of all probes and mixers

Check

- Status Monitor screen for error conditions
- Syringe plunger rods with attached tips for wear (replace if necessary)
- Hydropneumatic gauges for proper settings
- Wash concentrate, probe rinse solution
- Condition and orientation of cuvette wipers (adjust or replace if needed)

CX4 Weekly Maintenance

Flush

Sample and reagent pickup probes

CX4 Monthly Maintenance

Clean

- Reagent bar code reader window
- Refrigerator and power supply air filter
- Sample bar code reader window

Check

Proper orientation of refrigerator circulation fan and for condensation of ice buildup

Replace

In-line filter at probe rinse solution

CX4 Two-Month Maintenance

Check

All diluted wash bottle, DI water bottle, probe rinse bottle, and float sensors for contamination

Replace

Silicone wipers on cuvette washer probes; check for proper operation of cuvette washer probes

CX4 Three-Month Maintenance

Replace

Sample and reagent syringe plunger rods with attached tips

CX4 Six-Month Maintenance

Clean

All diluted wash bottles, probe rinse bottle, and float sensors

Replace

Wash concentrate in-line filter

Inlet water filter (located on back of instrument)

CHAPTER 9 Troubleshooting Chemistry Flags

Chemistry Flags

Introduction

All reactions are checked against chemistry parameter flag limits (e.g., Absorbance limits, reference ranges) to qualify the reagent, calibration, or sample. Checks are performed against the final result and on interim reaction data for all samples, including calibrators. Any calibrator or sample result or reaction step performing outside of any one or more limits will be flagged (message or remark). A flagged sample value will not be reported.

Flag Abbreviations for Reports

Table 9.1 lists the flag abbreviation and the flag name that appears on the calibration or result report.

Table 9.1 Flag Abbreviations for Reports

Abbreviation ^a	Name
BACK TO BACK	Back-to-Back
BL ABS HI (BH)	Blank Absorbance High
BL ABS LO (BL)	Blank Absorbance Low
BL MEAN DEV (BN)	Blank Mean Deviation
BL MAX DEV (BO)	Blank Max Deviation
BL RATE HI (SH)	Blank Rate High
BL RATE LO (SL)	Blank Rate Low
DAC	Digital to Analog Conversion
OCR HI	Out of Calibrator Range High
OCR LO	Out of Calibrator Range Low
REF DRIFT (DR)	Reference Drift
ERRATIC ADC (EA)	Erratic ADC
INT ABS HI (AH)	Initial Absorbance High
INT RATE HI (IR)	Initial Rate High
INC DATA	Inconsistent Data
MATH ERR 5	Calibrator Order Error for Multipoint Chemistry
MATH ERR #	Math Error/Nonoverrideable
MATH ERR #	Math Error/Overrideable

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Table 9.1 Flag Abbreviations for Reports, continued

Abbreviation^a	Name
NOISE (NT)	Noise Threshold
OIR ERR	Out of Instrument Electronic Range
OIR HIGH (HI)	Out of Instrument Range High
OIR LOW (LO)	Out of Instrument Range Low
OIR O HIGH (OH)	ORDAC High
OIR O LOW (OL)	ORDAC Low
ORR HIGH (UH)	Out of Reportable Range High
ORR LOW (UL)	Out of Reportable Range Low
ORR O HIGH (UO)	Out of ORDAC Reportable Range High
OUTLIER (OT)	Outlier Threshold
RECOVERY	Recovery
RX ABS HI (HR)	Reaction Absorbance High
RX ABS LO (LR)	Reaction Absorbance Low
RX MEAN DEV (RN)	Reaction Mean Deviation
RX MAX DEV (RO)	Reaction Max Deviation
RX RATE HI (RH)	Reaction Rate High
RX RATE LO (RL)	Reaction Rate Low
SENSITIVITY	Sensitivity
SEV RECOVERY	Severe Recovery
SEV SENSITIVITY	Severe Sensitivity
SPAN	Span
SUB DEPL (SD)	Substrate Depletion
TEMP ERR (TM)	Temperature Error
ADC ERROR	ADC Error

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^a The two letter codes in parentheses are the error codes which are transmitted to the host.

Flag Descriptions

Flag descriptions are summarized in Table 9.2.

Table 9.2 Flag Descriptions

Flag Name	Flag Description
Blank Absorbance (high/low)	Mean absorbance measured during the reagent blank spin cycles (read window). The units are in Absorbance and will characterize reagent quality.
Blank Maximum Deviation	A single blank absorbance data point obtained during the reagent blank read window deviates more than allowed from the line of regression. The units are in delta absorbance and will check for a constant rate during the blank spin cycles.
Blank Mean Deviation	The average difference between the absorbance readings and the line of regression is greater than allowed. This will check for a constant rate during the blank spin cycles.
Erratic ADCs	The difference between the high and low value of the four reference electrode readings (taken milliseconds apart) has exceeded the limits allowed. Units are in ADCs and are a measurement of noise in the ISE system.
Calibrator Order Error	Occurs in Sector mode when not all calibrator levels are in ascending order (low to high) and/or not all levels reside in the same sector.
Excessive Reference Drift	A CX3/ISE reference electrode measurement for a sample drifted above the reference electrode measurement from the calibration and/or from sample-to-sample and exceeded the limit. The units are in ADCs and are a measurement of CX3/ISE reference electrode drift.
Initial Absorbance High	The reaction absorbance data taken from the first spin cycle after sample inject has exceeded specifications. This is a measurement of sample integrity.
Initial Rate High	The reaction rate data obtained between 2 and 17 seconds after sample inject exceeds specifications.
Noise	During a particular spin cycle, the average difference between an absorbance reading and the line of regression exceeded specifications.

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Table 9.2 Flag Descriptions, continued

Flag Name	Flag Description
Outlier	During a particular spin cycle, the deviation of a single absorbance reading with respect to the line of regression exceeded specifications.
Out of Instrument Range (high/low)	The recovered value exceeds the value that the instrument will report.
Out of ORDAC Range (high/low)	A reaction exceeded the range of ORDAC (Over Range Detection And Correction) values that the instrument will report.
Out of Reportable Range (high/low)	The recovered value exceeds the reportable range limits.
Out of ORDAC Reportable Range (high)	A reaction exceeded the high ORDAC reportable range.
Reaction Absorbance (high/low)	The mean absorbance measured during the reaction spin cycles.
Reaction Maximum Deviation	A single reaction absorbance data point obtained during the reaction read window deviates more than allowed from the line of regression. The units are in delta absorbance and will check for a constant rate during the reaction read window.
Reaction Mean Deviation	The average difference between the reaction absorbance readings and the line of regression is greater than allowed This will check for a constant rate during the reaction spin cycles.
Reaction Rate (high/low)	The rate calculated during the reaction read window. Units are in delta Absorbance/minute.
Substrate Depletion	Difference (delta) between the initial absorbance taken after sample inject and the final absorbance data point within the reaction read window exceeds specification.
Temperature	The operating temperature of the system is beyond 0.1°C from the set point value. All CX4 Chemistry results will be reported with a flag.
ADC ERROR	More that 1 second elapsed between start and end of ADC conversion process.

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